**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF NEW YORK**

| | |
|---|---|
| CEROVENE, INC., and DR. REDDY'S LABORATORIES, INC.,<br><br>Plaintiffs,<br><br>v.<br><br>FUKUZYU PHARMACEUTICAL CO., LTD.,<br><br>Defendant. | Civil Action No. _____<br><br>**COMPLAINT** |

Plaintiffs Cerovene, Inc. ("Cerovene"), and Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's") ("Plaintiffs"), by and though their undersigned counsel, Greenberg Traurig, LLP, as and for their Complaint against Defendant Fukuzyu Pharmaceutical Co., LTD. ("Fukuzyu") allege as follows:

## NATURE OF THE ACTION

1. This case is based on Fukuzyu's involvement in an illegal scheme to monopolize the market for the life-saving pharmaceutical drug Daraprim® (generic: pyrimethamine), in which Fukuzyu intentionally and knowingly accepted a bribe to prevent Plaintiffs from competing in the Daraprim market. Daraprim, which is used to treat serios parasite infections (toxoplasmosis) of the body in people with HIV infections, is an old drug, first introduced in 1953, whose patents expired decades ago, but has become an important drug in the treatment of HIV infection. In 2015, Vyera Pharmaceuticals, LLC ("Vyera"), owned and controlled by the notorious "pharma bro" Martin Shkreli through its parent company Phoenixus AG ("Phoenixus"), acquired Daraprim, raised the price 4,000%, and then intentionally erected barriers for generic companies, such as Plaintiffs (which had already been developing a generic version of Daraprim), to develop and obtain approval for their generic version of Daraprim.

2. Fukuzyu is a co-conspirator that knowingly and intentionally played a key role in Vyera's illegal scheme beginning as early as December 2015, immediately after Phoenixus and Vyera acquired the drug Daraprim. Fukuzyu is a manufacturer of pharmaceutical products, and manufactured the active pharmaceutical ingredient ("API") in Daraprim, pyrimethamine. By 2016, Fukuzyu was the only manufacturer of Daraprim API that was approved by the Food and Drug Administration ("FDA"), and, in addition to supplying the API to Vyera, Fukuzyu had also agreed to supply the API to Cerovene for it to support use to obtain approval by the FDA of its pending Abbreviated New Drug Application ("ANDA") for a generic version of Daraprim.

3. However, before that supply deal could be inked, Vyera enlisted Fukuzyu in its antitrust conspiracy to refuse to sell Daraprim API to potential generic competitors, by promising Fukuzyu that Vyera would greatly expand their business relationship. Vyera was not shy about its purpose, and expressly advised Fukuzyu that it would only win Vyera's purportedly vast future business if Fukuzyu agreed not to supply generic companies with Daraprim API in order to prevent Vyera's competitors from coming to market. Greedy for that potential future business from Vyera, in late 2015 Fukuzyu agreed to Vyera's offer to buy off Fukuzyu in return for Fukuzyu agreeing not sell its Daraprim APA to any of Vyera's competitors, and Fukuzyu ultimately executed an exclusive license agreement promising that it would not sell Daraprim API to generic pharmaceutical companies for them to use to develop a competing generic version of Daraprim. Fukuzyu held up its part of the illegal deal, and Fukuzyu's President, Teruo Kosugi, abruptly cut off negotiations with Cerovene and refused to supply Cerovene with Daraprim API. Mr. Kosugi falsely advised Cerovene that Fukuzyu would not be selling Daraprim API "to anyone" because of purportedly "low business potential," but that was a lie. The real reason was because Fukuzyu was bought off by Vyera to assist Vyera in protecting its monopoly.

4. Fukuzyu's abrupt refusal to supply Daraprim API to Cerovene had its intended effect, and Cerovene and Dr. Reddy's were delayed in entering the Daraprim market because they were unable to source Daraprim API from Fukuzyu. That process would have taken less than a year under normal circumstances had Fukuzyu agreed to supply Cerovene with Daraprim API, and Cerovene's ANDA would have been approved by the FDA and launched by Dr. Reddy's in September 2017. However, Fukuzyu's agreement to refuse to supply Cerovene with Daraprim API delayed FDA approval of Plaintiffs' generic Daraprim ANDA by 30 months to March 2020.

5. In addition to depriving the patients who required the life-saving pharmaceutical of a less expensive generic version, that delay also deprived Cerovene and Dr. Reddy's of the profits they would have received in marketing and selling the first generic version of Daraprim which, during the thirty (30) month period from March 2020 through August 2022. These lost profits exceed $36 million.

6. In 2020, the Federal Trade Commission ("FTC") and several state attorneys general sued Vyera for violations of Sections 1 and 2 of the Sherman Act and analogous state laws based on its illegal scheme to prevent generic competition in the Daraprim market (the "FTC Action"). After a trial in late 2021, on January 14, 2022, Judge Denise Cotes issued a 135-page opinion finding that the conduct described in that opinion, and in this Complaint, violated Sections 1 and 2 of the Sherman Act.[1]

7. Plaintiffs now bring this action pursuant to Sections 4 and 5(i) of the Clayton Act, 15 U.S.C. §§ 15 and 16(i), to recover treble damages, plus attorney's fees and costs, for the injuries they suffered by reason of Fukuzyu's violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C.

[1] Judge Cotes' opinion is attached hereto as Exhibit A. This Complaint quotes extensively from Judge Cotes' opinion, which establishes the Defendants' illegal conduct that forms the basis of the Plaintiffs' claims.

§§ 1 and 2.

## JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1337(a), because Plaintiffs assert claims under Section 1 and 2 of the Sherman Act, 15 U.S.C. §§1 and 2, and Section 5 of the Clayton Act, 15 U.S.C. §15.

9. This Court has personal jurisdiction over Fukuzyu because this action arises out of and relates Fukuzyu's actions that directly and foreseeably resulted in harm to Plaintiffs in New York and Fukuzyu's actions taken in New York through a representative in New York. Specifically, Fukuzyu acted through a New York-based representative in its dealings with Cerovene and Dr. Reddy's that form the basis of this Complaint.

10. This Court has personal jurisdiction over Fukuzyu based on the following:

(a) Fukuzyu's co-conspirators in the antitrust conspiracy in which it knowingly participated, including Vyera, conducted extensive actions in furtherance of the conspiracy in in the United States and in this District, and those actions are attributed to all members of the conspiracy, including Fukuzyu. And, as a result, Fukuzyu was aware of the foreseeable and intended effect of the conspiracy and its participation in the conspiracy in the United States and in this District, which was to restrain and monopolize the market for Daraprim in the United States.

(b) Fukuzyu, either directly or through its United States FDA agent, filed a Drug Master File ("DMF") with the United States FDA for pyrimethamine in 1992 and has maintained the DMF as active in the United States since 1992 to date, including during the entire relevant time period when Fukuzyu conspired with Phoenixus and Vyera not to use its United States FDA-filed DMF to supply any competitors of Vyera, including

Plaintiffs.

(c) Fukuzyu negotiated with Cerovene (in New York) directly and through Fukuzyu's representative, Sumitomo Pharma, Fukuzyu's United States representative based in New York. And Fukuzyu supplied a sample of pyrimethamine for Cerovene in New York to assess for suitability, but once Fukuzyu entered into the conspiracy with Phoenixus and Vyera to restrain and monopolize the Daraprim market in the United States, Fukuzyu abruptly terminated negotiations with Cerovene and refused to supply Daraprim API to Cerovene. Pursuant to the conspiracy, Fukuzyu's President, Mr. Kosugi, sent a letter to Cerovene dated October 4, 2016 (attached hereto as Exhibit B), which was conveyed to Cerovene in New York through Fukuzyu's United States representative, a Sumitomo Pharma employee based in New York.

11. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b).

## THE PARTIES

12. Plaintiff Cerovene, Inc. ("Cerovene"), is a corporation incorporated under the laws of Delaware, with its principal place of business at 612 Corporate Way, Suite 10, Valley Cottage, New York 10989.

13. Plaintiff Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's"), is a corporation incorporated under the laws of Delaware, with its principal place of business at 107 College Rd E, Princeton, New Jersey 08540.

14. Defendant Fukuzyu Pharmaceutical Co., Ltd. ("Fukuzyu") is a corporation organized under the laws of Japan, with its principal place of business at 48, Hagiwara, Toyama, 939-8261, Japan.

## FACTUAL ALLEGATIONS

### A. Background – FDA Drug Approval Process for Generic Drugs

15. The illegal anticompetitive scheme at issue here unfolded against the backdrop of the U.S. regulatory process for the approval and sale of pharmaceutical drugs. The FDA is the federal agency that approves the sale of branded and generic drugs in the United States.

16. The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly known as the Hatch-Waxman Act, allows a generic manufacturer of an already approved brand-name drug to obtain expedited approval from the FDA to market the generic equivalent by filing an Abbreviated New Drug Application ("ANDA"). *See FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013). The ANDA process is designed to help expedite market introduction of low-cost generic drugs in order to further competition. *Id*.

17. Any pharmaceutical company applying for FDA approval of a generic competitor to a branded drug must obtain the API used in the branded drug -- that is, the drug's critical ingredient that provides its therapeutic effect -- from an approved supplier.

18. The API to be used in the generic drug is evaluated for impurities and stability. 21 C.F.R. §§ 211.165, 211.170.

19. An API supplier's manufacturing process must also comply with FDA standards known as current Good Manufacturing Practices ("cGMPs"). FDA regulations set minimum standards for the methods, facilities, controls, and documentation for manufacturing, processing, and packing of the pharmaceutical, including its API.

20. A pharmaceutical company may demonstrate that the manufacturing process of the API used in its drug product complies with cGMPs either by supplying that information to the

FDA in the ANDA itself (if it manufactures the API itself) or, more commonly, by referencing information filed by an API supplier with the FDA in a standalone Drug Master File ("DMF"). The FDA categorizes DMFs for APIs as Type II DMFs. To file a Type II DMF, an API supplier must pay a fee and submit enough materials, including confidential documents about the manufacturer's facilities, processing, packaging, and storing of human drug products, to permit the FDA to conduct a full scientific review for any ANDAs that reference the DMF. The FDA conducts a completeness assessment of an API supplier's newly-filed DMF at the time it is submitted, but does not fully review a DMF's documented manufacturing process for cGMPs compliance until the DMF is referenced in a new drug application ("NDA") or ANDA. 21 CFR § 314.420(a).

21. In order to obtain the API for a particular drug product a pharmaceutical company may invest in developing an API supplier's manufacturing processes, or it may shorten the process significantly by partnering with an API supplier that has already filed a DMF for the API. Because developing and documenting a cGMPs-compliant API manufacturing process from scratch is time-consuming and expensive -- it can take twelve to eighteen months or more and may cost over $1 million -- generic pharmaceutical companies prefer to use a supplier that already has an FDA-approved DMF for the API.

22. Therefore, any generic company that seeks to launch a product as fast as possible generally attempts to partner with a DMF-holding supplier whose API is already in use in another FDA-approved product. A less desirable option is partnering with an API manufacturer that currently produces the API but does not have a DMF filed in the U.S. The least attractive option is to develop a cGMPs-compliant manufacturing process from scratch, which is costly and can take years.

23. To foster price competition among pharmaceuticals, the law provides various incentives to pharmaceutical companies. *See* Generic Drug User Fee Act, 21 U.S.C. § 356h. These include the FDA's prioritization of its review of the first generic entrant to file an ANDA. The first generic drug product to enter a market in competition against the brand name drug is known in the pharmaceutical industry as the "first-to-market" generic.

24. Most state laws require that pharmacies must fill a prescription for a branded drug with its approved generic version, unless the prescription requires that the branded version be used. Generic drugs typically enter a market at a significant discount. As a result of the generic drug's price discount, and requirement to substitute an approved generic for the branded version, the entry of the first generic competitor typically results in price erosion of approximately 30% to 40% from the prevailing price of the brand-name drug, and the branded drug's sales volume also experiences a significant decline of approximately 60% to 70% when the first generic enters the market. Six months after generic entry, the brand name drug's sales will typically have fallen by 80-90%, or more. The branded drug's sales volume and price usually continue to decline as additional generic products enter the market.

**B. Daraprim**

25. Daraprim was first approved by the FDA in 1953, and approved by the FDA in 1958 for the treatment of toxoplasmosis, and its patents expired decades ago. Toxoplasmosis is a parasitic infection that can cause severe disease and death. The parasite is present in approximately 10% of the population, but is usually dormant. An opportunistic infection, toxoplasmosis principally impacts immunosuppressed and immunocompromised individuals such as patients who are HIV positive or recipients of organ transplants. Toxoplasmosis can cause disease in many parts of the body, but the most common manifestations are infections of the brain (toxoplasma

encephalitis), eye (ocular toxoplasmosis), and in utero. Toxoplasma encephalitis is the most common and acute presentation of the disease among immunosuppressed patients. Toxoplasmosis fatalities have dropped significantly since the launch of antiretroviral therapies in 1996, which significantly limited opportunities for a toxoplasmosis infection to become acute in HIV-positive patients. If an infection becomes active and advanced, a patient presenting with toxoplasma encephalitis could die within twelve to twenty-four hours unless treated. There is also a risk of severe brain damage in those who survive. As a result, physicians must have an effective treatment on hand to halt the progress of an active infection as quickly as possible.

26. The Opportunistic Infections Guidelines (the "Guidelines"), an authoritative publication on which physicians depend, gives its highest recommendation to a pyrimethamine-based regimen for the treatment of acute toxoplasmosis. Pyrimethamine is the API of Daraprim. The Guidelines rank recommended treatment options for certain diseases with a letter and a numeral. The letter grade signifies the strength of the recommendation and the Roman numerals indicate the quality of the evidence supporting the recommendation. Accordingly, an A-I grade is a recommendation based on the strongest, highest-quality evidence derived from randomized control clinical trials, or, if randomized control trials have not been conducted, methodologically sound cohort studies or meta-analyses. Lower grades are given to treatment options that have been shown to be effective but are not preferred, or are based on less methodologically reliable studies. Under the Guidelines, pyrimethamine plus sulfadiazine and leucovorin is given the strongest possible recommendation for treating active toxoplasma encephalitis: A-I. The recommended dosage of Daraprim, available only as a 25 milligram tablet, is an initial dose of 200 milligrams (eight pills) followed by 50 to 75 milligrams (two to three pills) daily for at least six weeks. For patients who cannot tolerate a sulfa drug, the recommended treatment is pyrimethamine plus

clindamycin.

27. The pyrimethamine-based regimen is preferred to alternative treatments because of its efficacy and safety, long history of successful clinical use, superior potency in comparison to other treatments, and diagnostic utility when a biopsy is not feasible. A significant decrease in the size, inflation, or number of lesions in the brain following a week or more of treatment confirms the diagnosis. Because a biopsy of the brain carries extreme risks, pyrimethamine's diagnostic utility is particularly important. Pyrimethamine remains the only drug approved by the FDA for the treatment of toxoplasmosis. And, until the entry of FDA-approved generic pyrimethamine in 2020, Daraprim was the only FDA-approved pyrimethamine product on the market.

## C. The Fukuzyu-Vyera Agreement

### 1. Daraprim's 2015 Price Hike

28. Vyera, then called Turing Pharmaceuticals LLC ("Turing"), was founded in October 2014. In April 2015, Vyera acquired the U.S. licensing rights to Daraprim from Impax Laboratories, Inc. ("Impax"). Within days of Vyera's purchase of Daraprim, Vyera raised the list price -- also called the wholesale acquisition cost ("WAC") -- from $17.60 to $750 per tablet, representing about a 4,000% increase. From roughly 2016 to 2019, the average net price of Daraprim (the price per tablet after subtracting discounts, chargebacks, and rebates off the WAC) ranged between $228 and $305 per tablet. Dr. Eliseo Salinas, Vyera's President of R&D between June 2015 and April 2017 and interim CEO between April and July 2017, testified during the trial in the FTC Action that the price hike was the "poster child of everything that is considered wrong about the pharmaceutical industry."

29. Daraprim revenues in the years between 2010 to 2014 (before it was acquired by Vyera) had amounted at most to $10 million a year. From 2016 through 2019, Vyera made between

$55 and $74 million in annual gross profits from its sales of Daraprim.

**2. Fukuzyu Agrees To Refuse To Supply Daraprim API To Cerovene**

30. Fukuzyu, an established and prominent pharmaceutical manufacturer, was the long-term supplier of pyrimethamine for Daraprim. Fukuzyu had been producing pyrimethamine since 1966, and is the manufacturer referenced in Daraprim's NDA.

31. Fukuzyu, either directly or through its United States FDA agent, filed a DMF with the United States FDA for pyrimethamine in 1992. The DMF is currently active, and upon information and belief, Fukuzyu maintained the DMF in the United States since 1992 to date, including during the entire relevant time period when Fukuzyu conspired with Phoenixus and Vyera not to use its United States FDA-filed DMF to supply any competitors of Vyera, including Plaintiffs.

32. The only other manufacturer to have filed a pyrimethamine DMF, Ipca, had lost its right to sell pyrimethamine in the United States in 2015. As the only holder of a pyrimethamine DMF, Fukuzyu was the most attractive supplier of pyrimethamine to companies seeking to develop a generic version of Daraprim.

33. Upon its acquisition of Daraprim in 2015, Vyera immediately enlisted Fukuzyu in its antitrust conspiracy to prevent generic competition, and convinced Fukuzyu to refuse to sell pyrimethamine API to U.S.-based generic drug companies through an exclusive supply agreement.

34. Upon information and belief, Fukuzyu joined Vyera's antitrust conspiracy before October 2016, when Vyera travelled to Japan to meet with Fukuzyu in furtherance of the conspiracy.

35. Upon information and belief, Fukuzyu generally does not enter into exclusive supply agreements with its customers under similar circumstances. For example, Fukuzyu sold Daraprim

API to Impax, the company from which Vyera purchased Daraprim, without even entering into a supply contract. Fukuzyu also sells Daraprim API to GlaxoSmithKline, which holds the worldwide rights to Daraprim outside of North America. Fukuzyu also does have a supply contract with GlaxoSmithKline but, upon information and belief, that contract does not have any provision that prohibit Fukuzyu from selling Daraprim API to other customers in the applicable regions.

36. However, Fukuzyu agreed to reverse that practice for Vyera -- to refuse to sell to Vyera's potential competitors in order to prevent them from being able to develop a competing version of Daraprim. Vyera represented to Fukuzyu that it had several ambitious projects and hoped to use Fukuzyu as a long-term API supplier for each of those projects. Fukuzyu was well aware of the reason for exclusivity, because Vyera bluntly explained to Fukuzyu that it needed an exclusive supply contract to prevent generic Daraprim from entering the United States market and to thereby restrain trade in and monopolize the market for Daraprim in the United States (which was the only area in which Vyera had rights for Daraprim)..

37. Various Vyera employees warned Fukuzyu that its promise of significant future business and huge profits would only work if Fukuzyu helped it prevent competition in the Daraprim market. For example, in November 2016, through a consultant, Vyera informed Fukuzyu that "[i]f generic products are put on the U.S. market" Vyera will face a "serious problem, and may eventually terminate the marketing of Daraprim as well as the R&D in toxoplasmosis"; that generic pyrimethamine "will hamper" Vyera's plans to develop new pharmaceutical products and "may leave toxoplasmosis as a forgotten disease with insufficient therapeutic effects"; and that Vyera's plans are "ONLY POSSIBLE" if Vyera has exclusive access to Fukuzyu's API. The consultant was also to stress that Fukuzyu would "not benefit" if generic companies sold pyrimethamine in the U.S. market since generic companies would sell pyrimethamine at a

"significantly lower" price.

38. Thus, in furtherance of the conspiracy, Fukuzyu agreed not to sell pyrimethamine "to generic companies" in exchange for Vyera's promise of future business.

39. According to Vyera's consultant, Fukuzyu's President, Mr. Kosugi, was particularly pleased that Vyera planned to "develop four more new compounds and would like [Fukuzyu] to work together" with it on those compounds.

40. On January 25, 2017, Fukuzyu entered into a three-year exclusive supply agreement with Vyera's parent company. That contract merely memorialized the earlier agreement in furtherance of the conspiracy. The exclusivity term states that,

> [Fukuzyu] shall provide the API Bulk Drug Substance, pyrimethamine exclusively to [Vyera's parent] for the use, sale, and/or distribution in the Territory. To be clear, the use, sale, and/or distribution of pyrimethamine described in this section refers to the use, sale, and/or distribution of the API Bulk Drug Substance for humans only.

41. The Territory was defined as the United States, thereby making it clear and foreseeable to Fukuzyu that the effect of the agreement would prevent competition only in the United States and to restrain and monopolize the market for Daraprim in the United States.

42. There was no justification for Fukuzyu to enter into an exclusive supply agreement with Vyera other than to conspire with Vyera and Phoenixus to restrain and monopolize the market for Daraprim in the United States. Indeed, Vyera, and the other owners of Daraprim before it, were always able to obtain pyrimethamine from Fukuzyu, and never had any supply issues.

43. Moreover, Vyera's contract with Fukuzyu contained no provision that protected it against the risk that Fukuzyu might be unable to supply Vyera with FDA-approved pyrimethamine. For example, it contained no provision requiring Fukuzyu to maintain cGMPs-compliant facilities, to ensure the purity of its API, or to keep an active DMF.

44. There are standard provisions that protect against the risk of a loss of supply. Those

provisions were absent in the Vyera contracts, but tellingly, were present in the GSK contract with Fukuzyu. Those provisions include clauses addressed to the forecasting of requirements, customer priority, reserve capacity, and firm order dates.

45. It contained no provision to ensure that Vyera will have a supply of pyrimethamine or require Fukuzyu to prioritize Vyera's orders over those from its other customers. It did not, for instance, require Vyera to forecast its API requirements or obligate Fukuzyu to reserve any quantity of pyrimethamine or manufacturing capacity to produce pyrimethamine.

46. It did not even require Fukuzyu to fill a Vyera order. Under the agreement, Vyera was required to submit a purchase order to Fukuzyu. If Fukuzyu did not acknowledge the order in writing within ten days, it had no obligation to fill the order. The agreement stated that:

> [Daraprim] is historically a low volume product for [Vyera]. Due to the infrequent need to manufacture [Daraprim], [Vyera] will provide [Fukuzyu] a Firm Order for API, in the form of a Purchase Order. Receipt of the Purchase Order denotes [Vyera]'s binding request to purchase API within 180 days of date of Purchase Order. [Fukuzyu] will accept Firm Orders by sending an acknowledgement to [Vyera] within 10 business days of its receipt of the Firm Order.

47. There is nothing in the agreement that prevented Fukuzyu from selling its entire inventory of pyrimethamine to others for use outside the United States or for the treatment of animals in the United States.

48. Moreover, while it may be common for companies to enter into exclusive supply agreements with API manufacturers when a company has invested time and money with that manufacturer to develop a new API manufacturing process, there was no such justification here. Fukuzyu already had a DMF on file and had been supplying pyrimethamine for Daraprim for decades.

49. Other than a desire to block competition, there was no reason to tie Fukuzyu to exclusive supply agreements, and there was no reason why Fukuzyu would accept the exclusive

arrangement.

50. The only reason for the contract was to memorialize Fukuzyu's agreement to not supply Vyera's competitors.

**D. The Fukuzyu-Vyera Agreement Violated Section 1 of the Sherman Act**

51. Section 1 of the Sherman Act outlaws "[e]very contract, combination . . . , or conspiracy, in restraint of trade or commerce among the several States." 15 U.S.C. § 1. An illegal restraint of trade is demonstrated where there was a combination or some form of concerted action between at least two legally distinct economic entities that constituted an unreasonable restraint of trade.

52. Fukuzyu's agreement constitutes unreasonable restraint of trade in violation of § 1 of the Sherman Act.

53. The restraint exploited features of the FDA approval process for generic drug products by unreasonably and unlawfully restricting the market for API. This agreement violated § 1 of the Sherman Act.

54. Vyera and Fukuzyu intended to block generic competition to Daraprim and strove to do so for as long as possible. Fukuzyu's contract was entered in service of that strategy, and achieved its intended effect, by successfully closing off access to the most viable supplier of pyrimethamine for years, delaying the entry of generic pyrimethamine into the market.

**E. The Fukuzyu-Vyera Agreement Delayed Plaintiffs From Launching A Competing Daraprim Product For Almost Three Years**

55. Vyera's campaign to delay the entry of generic pyrimethamine succeeded in substantially delaying the entry Cerovene and Dr Reddy's, by making it exceedingly difficult for them to obtain the pyrimethamine API.

56. Cerovene is a pharmaceutical research and development firm based in New York,

with a specialty in developing generic pharmaceutical products. Cerovene began developing generic Daraprim in 2013 and first submitted its Abbreviated New Drug Application ("ANDA") to the FDA in 2014. Dr. Reddy's is a pharmaceutical development and marketing company headquartered in Princeton, New Jersey, which specializes in the development and marketing of generic pharmaceutical products in the United States. Cerovene partnered with Dr. Reddy's to market and sell Cerovene's generic Daraprim product under and pursuant to a Development and Supply Agreement between Cerovene and Dr. Reddy's.

57. Cerovene's initial development of its generic Daraprim product went smoothly because, in 2013 and 2014 (before Vyera acquired Daraprim), it was able to easily procure a supplier of Daraprim API. Supply of the API is essential to the development and FDA approval of a generic drug. However, while Cerovene's ANDA was pending, the FDA imposed an import ban on Cerovene's API supplier, so Cerovene needed to engage a new API supplier before its ANDA would be approved. By that time, Fukuzyu was the only FDA-approved supplier of Daraprim API.

58. So, Cerovene sought to contract with Fukuzyu to supply it with Daraprim API to support its development of a generic version of Daraprim.

59. Cerovene first contacted Fukuzyu in 2015, and Fukuzyu welcomed the opportunity to supply Daraprim API to Cerovene. Fukuzyu negotiated with Cerovene (in New York) directly and through a Fukuzyu's representative, Sumitomo Pharma, Fukuzyu's United States representative based in New York. Fukuzyu supplied a sample of pyrimethamine for Cerovene to assess for suitability. Negotiations went smoothly, and by September 2016, Cerovene believed that Fukuzyu had agreed to supply Cerovene with pyrimethamine to develop its generic product.

60. However, unbeknownst to Plaintiffs, Fukuzyu was simultaneously negotiating an illicit deal with Vyera pursuant to which Fukuzyu would refuse to supply Daraprim API to Vyera's

potential generic competitors. Once that deal was struck, Fukuzyu abruptly terminated negotiations with Cerovene and refused to supply Daraprim API to Cerovene. Fukuzyu's President, Mr. Kosugi, sent a letter to Cerovene dated October 4, 2016 (attached hereto as Exhibit B), which was conveyed to Cerovene in New York through Fukuzyu's United States representative, a Sumitomo Pharma employee based in New York. In the letter, Fukuzyu advised Cerovene:

> We, Fukujyu Pharmaceutical Co., Ltd., officially determined not to accept your request for "Pyrimethamine" supply.
>
> Pyrimethamine is a very old drug substance and the demand is not expected to grow substantially since its usage is limited. Therefore, after thorough consideration, we concluded not to supply this item to anyone because of low business potential and high risk associated with the business.
>
> Thank you for understanding.

61. That statement by Mr. Kosugi was a lie to conceal the exclusive dealing arrangement between Fukuzyu and Vyera to preserve Vyera's monopoly on Daraprim. Rather than determining that there was low business potential and high risk associated with Daraprim API, as described above, Fukuzyu had already agreed to supply Vyera with Daraprim API, and the reason Fukuzyu refused to do the same for Cerovene was not because of any analysis of the potentials and risks of the business, but because it had been bought off by Vyera.

62. While the pyrimethamine manufacturing process is relatively simple, it still takes time and money to design the process, set it up, and test it. Shut out of access to Fukuzyu's API, Cerovene and Dr. Reddy's were required to undertake a time-consuming and costly journey to develop an alternative API manufacturer.

63. In November 2016, Cerovene entered a five-year exclusive supply agreement with another API manufacturer for the supply of Daraprim API, but that manufacturer did not have an

FDA-approved DMF for Daraprim API, so Cerovene needed to pay it to do so. Specifically, Cerovene entered an agreement that obligated the manufacturer to provide a pyrimethamine DMF that would be referenced in an amendment to Cerovene's ANDA. In return, Cerovene paid the manufacturer $100,000, with another $100,000 due upon approval of its ANDA. In sum, Cerovene incurred approximately $487,746 in development costs to obtain an alternat supplier of Daraprim API.

64. On April 2, 2017, Cerovene submitted a major amendment to its ANDA changing its API supplier. Because of the switch in supplier, the FDA issued a complete response letter to Cerovene's amended ANDA dated December 26, 2017, requiring Cerovene to conduct new testing using the new API. Cerovene eventually completed that testing, and submitted its results to the FDA in September 2019. Then, on February 28, 2020, Cerovene's generic pyrimethamine product received FDA approval and an AB rating to Daraprim. Dr. Reddy's launched the generic on March 20, 2020.

65. Cerovene's and Dr. Reddy's entry into the market was delayed by roughly thirty months, that is, from September 2017 to its actual entry date of March 2020. This timeline is premised on Cerovene having been able to obtain API from Fukuzyu in October 2016. Cerovene would have needed approximately eleven months to obtain approval for an amended ANDA in these circumstances. It would have taken one month to manufacture a registration batch of the generic drug product. Cerovene would have redone the testing necessary after changing API manufacturers and would have filed an amended ANDA changing Cerovene's API supplier to Fukuzyu in or around February 2017. Assuming that the FDA would have taken six months to review of Cerovene's amendment, it would have approved Cerovene's ANDA by August 2017. Dr. Reddy's would have launched Cerovene's FDA-approved generic pyrimethamine one month

later, in September 2017.

**F. Damages Suffered By Cerovene and Dr. Reddy's**

66. Cerovene's and Dr. Reddy's injury and damages to their business and property suffered directly as a result of Fukuzyu's actions and antitrust violations are: (a) the additional costs Cerovene would not have incurred, and (2) the lost profits Cerovene and Dr. Reddy's would have made, had Vyera not engaged in its antitrust violations, had Cerovene and Dr. Reddy's been able to use the existing API manufacturers for the supply of pyrimethamine API, and had Cerovene and Dr. Reddy's been able to launch and market their generic version of Daraprim during the 30-month period from September 2017 through March 2020 -- as found by the Court in the *FTC Action*.

67. The unnecessary development costs Cerovene incurred to obtain an alternate API supplier of pyrimethamine API were approximately $487,746.

68. The best yardstick and measure for the establishment of the lost profits is the profits Cerovene and Dr. Reddy's actually did earn in the first 30-months after they launched and marketed the product in competition with Vyera's Daraprim, from March 2020 through August 2022.

69. For Cerovene, those lost profit damages took the form of additional profit share payments that it would have received from Dr. Reddy's pursuant to the parties' Joint Development and Supply Agreement during the time period September 2017 through March 2020.

70. Dr. Reddy's lost profit damages took the form of the profits (net of costs and payments to Cerovene) it would have realized from the sale of generic Daraprim.

71. As set forth in Exhibit C, when Cerovene and Dr. Reddy's launched their generic Daraprim product in March 2020, during the first thirty months (from March 2020 to August 2022), Cerovene received a total of $20,227,692 in profit share payments from Dr. Reddy's, and Dr. Reddy's gross margin (after costs and profit share payments to Cerovene) was $16,027,649.

72. The foregoing amounts are accurate reflections of the profits Cerovene and Dr. Reddy's *would have* received during the thirty months beginning in September 2017, if Cerovene and Dr. Reddy's had been able to launch in September 2017 but for Fukuzyu's antitrust violations.

73. In sum, Cerovene's total actual damages (unnecessary API development costs incurred and lost profits) are $20,715,438, and Dr. Reddy's total damages (lost profits) are $16,027,649.

74. Under Section 4 of the Clayton Act, 15 U.S.C. § 15, Cerovene and Dr. Reddy's are entitled to treble damages (plus attorney's fees and costs). Accordingly, Cerovene would be entitled to a judgement in the amount of $62,146,314 (plus interest, attorney's fees and costs); and Dr. Reddy's would be entitled to a judgement in the amount of $48,082,947 (plus interest, attorney's fees and costs).

75. In total, on a combined basis, Cerovene and Dr. Reddy's are entitled to a total judgment of **$110,229,261** (plus interest, attorney's fees and costs).

## PLAINTIFFS' CLAIMS AGAINST DEFENDANT[2]

### COUNT I
### Violation of 15 U.S.C. §1
### Agreement in Restraint of Trade and Commerce in Daraprim in the United States

76. Plaintiffs re-allege and incorporate by reference the allegations in paragraphs 1 through 75, above.

77. Fukuzyu's exclusive pyrimethamine API contract with Vyera, which was conceived,

[2] Under Section 5(i) of the Clayton Act, 15 U.S.C. §16(i), the 4-year statute of limitations for a private antitrust action is suspended and tolled during the pendency of a suit by the United States under the antitrust laws, and for one year thereafter (after all appeals are exhausted), so long as the private suit is based on the same matter complained of in the government's case. The Supreme Court has held that a suit by the FTC to enforce the antitrust laws qualifies as a suit by the United States under Section 5(i). *See Minnesota Mining & Mfg. Co. v. New Jersey Wood Finishing Co*., 381 US 311, 321-22 (1965) ("[T]he limitation provision of § 4B is tolled by Commission proceedings to the same extent and in the same circumstances as it is by Justice Department actions."). The suspension period continues through the exhaustion of all appeals by any defendants, even they if they are not the parties being sued in a private suit. *See Russ Togs, Inc. v. Grinnell Corp*., 426 F.2d 850, 857-58 (2d Cir. 1970); *Marine Firemen's Union v. Owens-Corning Fiberglas Corp*., 503 F.2d 246, 249 (9th Cir. 1974).

The limitations suspension period begins when the government's suit (the *FTC Action*) was filed (in this case, January 27, 2020) and would then extend back 4 years, to begin on January 27, 2016, with Cerovene's

negotiated, signed, and/or enforced, is an unreasonable restraint of trade. As a result, Fukuzyu participated in an unlawful contract, combination and conspiracy in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

78. The Plaintiffs were injured in their business or property by reason of Fukuzyu's unlawful and anticompetitive acts.

**COUNT II**
**Violation of 15 U.S.C. §2**
**Conspiracy to Monopolize the Daraprim Market in the United States**

79. Plaintiffs re-allege and incorporate by reference the allegations in paragraphs 1 through 78, above.

80. Fukuzyu's conspired with Vyera and Phoenixus to monopolize the United States market for Daraprim in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

81. The Plaintiffs were injured in their business or property by reason of Fukuzyu's unlawful and anticompetitive acts.

**PRAYER FOR RELIEF**

WHEREFORE, Cerovene and Dr. Reddy's demand judgement against Defendant Fukuzyu providing the following relief:

A. An award to Cerovene and Dr. Reddy's of treble damages consisting of three times the

---

and Dr. Reddy's injuries being sustained in 2017-2020, when they would have entered the market but for Vyera's unlawful conduct. The suspension of the limitations period is continuing because the judgment in the FTC Action is the subject of a pending appeal in the United States Court of Appeals for the Second Circuit.

The outcome of the government's case (in the *FTC Action*) does not affect the tolling of the statute of limitations for private actions; however, under Section 5(a) of the Clayton Act, 15 U.S.C. §16(a), if the government prevails the judgement is *prima facie* evidence of a violation, and collaterally estops any defendants against whom the government obtained a judgement and prevailed.

damages they suffered to their business and property as a result of Defendant's unlawful conduct and antitrust violations, of **$110,229,261**, consisting of treble damages of $62,146,314 for Cerovene and treble damages of $48,082,947 for Dr. Reddy's;

B. An award to Cerovene and Dr. Reddy's of pre- and post-judgment interest;

C. An award to Cerovene and Dr. Reddy's of their attorneys' fees, costs, and expenses incurred in bringing this action;

D. An award to Cerovene and Dr. Reddy's of any and all other relief to which they may show themselves to be entitled; and,

E. An award to Cerovene and Dr. Reddy's of any other or further relief that the Court may deem just, proper or equitable under the circumstances.

Date: January 22, 2024

*/s/ Roger B. Kaplan*

Roger B. Kaplan, Esq.
Eric D. Wong, Esq.
GREENBERG TRAURIG, LLP
500 Campus Drive, Suite 400
Florham Park, New Jersey 07932
Tel: (973) 360-7900
Fax: (973) 301-8410
-and-
GREENBERG TRAURIG, LLP
One Vanderbilt Avenue
New York, NY 10017
Tel: (212) 801-9200
Fax: (212) 801-6400
Emails: kaplanr@gtlaw.com
wonge@gtlaw.com
*Attorneys for Plaintiffs Cerovene, Inc., and Dr. Reddy's Laboratories, Inc.*